

Complete Summary

GUIDELINE TITLE

Antiretroviral treatment of HIV infection.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Antiretroviral treatment of HIV infection.
New York (NY): New York State Department of Health; 2003 Mar. 64 p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Acquired immunodeficiency syndrome (AIDS)
- Adverse effects of antiretroviral therapy, including:
 - Bone marrow suppression
 - Dyslipidemia
 - Glucose intolerance
 - Pancreatitis
 - Lactic acidosis/hepatic steatosis
 - Hepatotoxicity
 - Renal toxicity
 - Myopathy/myositis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Hematology
Infectious Diseases
Internal Medicine

INTENDED USERS

Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop guidelines for antiretroviral treatment of human immunodeficiency virus (HIV)-infection

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients

INTERVENTIONS AND PRACTICES CONSIDERED

Laboratory Monitoring

1. Viral load (plasma viral load, CD4 cell counts, branched chain DNA [bDNA] assay)
2. Lymphocyte subsets (CD4 cell counts)
3. HIV resistance assays (genotypic assays, phenotypic assays, virtual phenotype)
4. Antiretroviral serum levels (therapeutic drug monitoring)
5. Laboratory monitoring of antiretroviral therapy side effects
 - Bone marrow suppression (complete blood counts, cytopenia)
 - Dyslipidemia (fasting serum lipid profile)
 - Glucose intolerance (monitoring of blood glucose levels every 3-4 months or as clinically indicated)
 - Pancreatitis (serum amylase and lipase levels)
 - Lactic acidosis/hepatic steatosis (lactate levels and serum bicarbonate levels; arterial blood gas analysis)
 - Hepatotoxicity (serum liver enzyme levels)
 - Renal toxicity (serum creatinine levels)
 - Myopathy/myositis (serum creatinine phosphokinase [CPK])

Treatment/Management

1. Initiation of HAART (Highly Active Antiretroviral Therapy)
 - Patient involvement in treatment initiation and planning
 - Maximization of viral load reduction
 - Patient education and counseling on risks and benefits of therapy and measures to reduce HIV transmission
2. Assessment and insurance of patient adherence to therapy
3. Selecting and initial antiretroviral regimen
 - For ARV-naïve patients, combination of two nucleoside reverse transcriptase (NRTI) inhibitors (e.g., didanosine, lamivudine, zidovudine, stavudine, tenofovir, abacavir) plus either a protease inhibitor (e.g., amprenavir, nelfinavir, indinavir, ritonavir, lopinavir, saquinavir); a non-nucleoside reverse transcriptase inhibitor (NNRTI) (e.g., nevirapine), or a third NRTI
 - Patient education on medication schedules, strict adherence, and side effects of therapy
4. Patients previously treated with only nucleoside analogs
 - Maintenance of previous therapy and observation only
 - Switch to HAART if suboptimal response
5. Changing a successful HAART regimen because of drug toxicity
6. Failure to achieve goals of initial HAART (i.e., failure of drop in viral load)
 - Obtaining results of viral resistance assays
 - Treatment intensification
7. Rescue/salvage therapy
 - Lab tests of HIV drug resistance and individualized ARV histories
 - Use of novel ARV drugs, such as enfuvirtide or T-20
8. Treatment of acute HIV infection
 - Testing for HIV in suspicious patients: quantitative HIV ribonucleic acid [RNA] or p24 antigen testing, with confirmatory HIV antibody testing
 - Patient involvement in decision to treat
9. Management of treatment interruption (voluntary, involuntary, and strategic interruptions)
10. Patient referral to research studies
11. Expanded access or compassionate use therapies
12. Referral to drug references to avoid therapy interactions with psychotropic medications

MAJOR OUTCOMES CONSIDERED

- Effectiveness of antiretroviral therapy in suppressing human immunodeficiency virus (HIV) replications
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3-4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Goals, Benefits, and Risks of Highly Active Antiretroviral Therapy (HAART)

Practitioners should prescribe a HAART regimen that is best able to delay disease progression, prolong survival, and maintain quality of life through maximal viral suppression.

Goals of Antiretroviral Therapy

- Maximal and durable suppression of viral replication (measured by viral load assays)
- Restoration and/or preservation of immune function
- Reduced human immunodeficiency virus (HIV)-related morbidity and mortality
- Improved quality of life
- Limitation of the likelihood of viral resistance to preserve future treatment options

The healthcare practitioner should involve the patient in the decision-making process when deciding whether to implement antiretroviral (ARV) therapy. The practitioner should review the benefits and risks of treatment for each individual patient.

Laboratory Monitoring

Monitoring of HIV-Infected Patients

Viral Load

In ARV treatment-naïve patients or patients who are on a successful regimen, plasma viral load should be measured at baseline and every 3 to 4 months thereafter. Patients with CD4 counts >500 cells/mm³ may require less frequent monitoring.

Viral load should be measured immediately before initiation or change of ARV therapy and every 4 to 8 weeks after initiation or change until maximal suppression is documented. Once maximal suppression is attained, monitoring of viral load should take place every 3 to 4 months.

If there is a significant increase (3-fold increase or more) in viral load without clear explanation, measurement should be repeated to confirm virologic failure.

Virologic failure should prompt the practitioner to assess the patient's adherence and to check for the presence of viral resistance.

When infection with a non-clade B strain is suspected, a branched chain DNA (bDNA) assay should be used to measure viral load.

Lymphocyte Subsets

CD4 cell counts should be measured at the time of diagnosis of HIV infection and every 3 to 6 months thereafter.

The absence of a significant CD4 cell count increase should not be interpreted as treatment failure if the viral load declines appropriately.

HIV Resistance Assays (See Table below)

Genotypic resistance testing should be performed before initiating treatment in ARV therapy-naïve patients to determine whether they were infected with drug resistant virus.

Resistance testing should be performed promptly in cases of virologic failure or incomplete viral suppression.

Resistance testing should be performed when patients are receiving therapy or have been off therapy for no more than 1 year.

When resistance tests are obtained, expert advice in interpretation is strongly encouraged.

Table: Recommendations for the Use of Drug Resistance Assays

Clinical Setting/Recommendation	Rationale
Recommended	
Virologic failure during HAART	Determine the role of resistance in drug failure, and maximize the number of active drugs in the new regimen.
Suboptimal suppression of viral load after initiation of ARV therapy (In	Determine the role of resistance, and maximize the number of active drugs in

Clinical Setting/Recommendation	Rationale
pregnant women initiating therapy, the clinician may not have as much time to monitor for suboptimal suppression.)	the new regimen if indicated.
Acute HIV infection; HIV infection of <3 years	Determine if drug-resistant virus was acquired so that an appropriate regimen may be chosen.
Not generally recommended	
HIV infection of >3 years prior to initiation of ARV therapy	Uncertain prevalence of resistant virus. Current assays may not detect minor drug-resistant species.
More than 1 year after discontinuation of drugs	Drug-resistant mutations may become minority species in the absence of selective drug pressure and may not be detectable. Current assays may not detect minority drug-resistant species.
Plasma viral load <250 HIV RNA copies/mL	Resistance assays cannot be reliably performed because of the low copy number of HIV RNA.

Antiretroviral Serum Levels (Therapeutic Drug Monitoring)

Monitoring blood levels of ARV drugs is not currently recommended.

Laboratory Monitoring of Antiretroviral Therapy Side Effects

Bone Marrow Suppression

Complete blood counts should be measured before initiation of ARV therapy and every 3 to 4 months thereafter. For patients at high risk for bone marrow toxicity (e.g., those with advanced HIV infection, those with pre-treatment cytopenias, or those who are receiving zidovudine or hydroxyurea), blood counts may have to be monitored more frequently (e.g., monthly) because significant cytopenias may occur.

Dyslipidemia

In patients receiving protease inhibitors (PIs) or non-nucleoside reverse transcriptase inhibitors (NNRTIs), a baseline fasting serum lipid profile should be determined before beginning therapy and within 3 months after starting therapy.

Follow-up fasting serum lipid profiles should be checked annually or as guided by the presence of other risk factors and/or the result of the 3-month post-treatment profile.

Appropriate treatment of dyslipidemia should be guided by the published guidelines of the National Cholesterol Education Program (NCEP) and the Adult AIDS Clinical Trial Group (ACTG) Cardiovascular Disease Focus Group. (See Tables 5 through 7 in the original guideline document.)

Glucose Intolerance

In patients receiving protease inhibitors, blood glucose levels should be monitored at baseline and every 3 to 4 months or as clinically indicated. (See Table 8 in the original guideline document for criteria to judge diabetes mellitus.)

Pancreatitis

Patients receiving ARV agents that are associated with pancreatitis should have serum amylase and lipase levels obtained when they present with signs or symptoms suggestive of pancreatitis.

An elevated serum amylase level should be confirmed with a serum lipase level.

Lactic Acidosis/Hepatic Steatosis

Any patient developing symptoms consistent with lactic acidosis syndrome in conjunction with an elevated lactate level (>2 mmol/L) and decreased serum bicarbonate (<20 mmol/L) should have his/her entire ARV regimen temporarily discontinued while an evaluation is conducted.

Routine monitoring of serum lactate levels is not indicated in asymptomatic patients.

Patients who are asymptomatic and have an unexplained decrease in serum bicarbonate level (<20 mmol/L) should be promptly re-evaluated with a repeat test and a venous or arterial lactate. If the lactate is mildly elevated (2.1 to 5.0 mmol/L), the lactate should be repeated, an arterial blood gas should be obtained, and reassessment for the presence of symptoms associated with lactic acidosis should be performed. If the lactate is persistently elevated, the arterial pH is abnormal, or the patient has become symptomatic, ARV therapy should be discontinued.

Hepatotoxicity

Serum liver enzyme levels should be obtained at baseline and every 3 to 4 months thereafter in patients receiving HAART.

Full-dose ritonavir (600 mg twice daily) should be avoided in patients with preexisting liver disease.

In the setting of hepatotoxicity related to nevirapine, patients should not be rechallenged.

Renal Toxicity

Serum creatinine levels should be measured at baseline and every 3 to 4 months thereafter in HIV-infected patients.

Myopathy/Myositis

Measurement of serum creatinine phosphokinase (CPK) is not routinely indicated.

HIV infection may be associated with asymptomatic elevation of CPK. In this setting, serial monitoring is not indicated.

If the patient becomes symptomatic (e.g., muscle pain or weakness), CPK should be measured.

Initiating Therapy

Patients should be involved in planning the treatment regimen and should agree to it before therapy is initiated.

Initiation of HAART is recommended when:

- Patient-related barriers to adherence are minimized.
- Centers for Disease Control and Prevention-defined AIDS or HIV-associated signs or symptoms are present.
- CD4 counts are <350 cells/mm³ OR viral load is $>55,000$ as determined by reverse transcriptase-polymerase chain reaction (RT-PCR) or bDNA.

Practitioners should devise initial HAART to achieve maximal viral load reduction (<50 copies/mL), which may take up to 6 months to achieve.

Healthcare practitioners should involve their patients when deciding which HAART regimen is most likely to result in adherence.

The individualization of a HAART regimen for a particular patient requires more than a single clinical visit, except in unusual circumstances.

The patient should be allowed to make the final decision of when to initiate therapy after counseling has taken place regarding specific issues relevant to his/her own clinical situation.

The practitioner should encourage strict safe-sex practices and avoidance of needlesharing activity for all patients, regardless of viral load, to prevent HIV transmission or superinfection.

The decision to begin ARV therapy should be individualized, made in the context of careful patient counseling and education, and based on an assessment of four major factors:

- The patient's risk of progression to illness or death if left untreated (see Figure 1 in the original guideline document)
- The patient's willingness to adhere to the therapy prescribed
- The presence of adherence obstacles

- The risk of long-term toxicity

The Importance of Patient Adherence

A team approach to achieving adherence should be used. Nurses, pharmacists, peer counselors, caseworkers, and others who work in outreach, evaluation, and support of adherence should be involved.

The practitioner should assess treatment readiness prior to initiation of treatment, adherence readiness for subsequent regimens, and adherence at every clinical visit. Interventions should be intensified in times of decreased adherence.

Practitioners should not base assumptions of adherence on patient characteristics but rather should consider all of the issues that have been shown to influence a patient's ability to adhere to a prescribed regimen.

Information about patients' beliefs and attitudes should be communicated with all members of the healthcare team so that each practitioner can consistently address treatment adherence issues within the context of the overall treatment plan.

If the patient is not fully committed to adhering to therapy, treatment should be delayed, and the practitioner should continue to work on abating the patient's concerns. Appropriate referrals should be provided for support groups, mental health, and drug treatment.

See the original guideline document for specific interventions related to the following aspects of patient adherence:

- The Patient-Healthcare Team Relationship: Involving the Patient
- Barriers to and Predictors of Adherence
- Educating the Patient About Adherence
- Patients' Beliefs and Attitudes
- Substance Use and Adherence
- How the Regimen Affects Adherence

Selecting an Initial Antiretroviral Regimen

For ARV therapy-naïve patients, the initial HAART regimen should include a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) plus either a PI, an NNRTI, or a third NRTI.

The goal of initial HAART in the ARV therapy-naïve patient should be to devise a regimen that will achieve maximal durable viral suppression (<50 copies/mL) and be tolerated for an indefinite period of time.

Patients starting ARV therapy should be counseled thoroughly concerning the need for strict adherence and the risk of viral drug resistance when adherence is compromised. If any medication needs to be interrupted, all medications should be stopped and restarted simultaneously. This counseling should be reinforced at regular intervals during the course of therapy.

Education should include the following elements:

- A written schedule of daily activities relating medication doses to sleep, meals, and work.
- Anticipation of likely side effects and education regarding the probable course of side effects.
- Exploration of potential obstacles to adherence and strategies for overcoming them.
- An offer of adherence supports (e.g., pillboxes, reminder beepers).
- Instruction that if any medication must be interrupted for more than several days (e.g., because of lack of supply or intolerable side effects), all ARV medications should be stopped and restarted simultaneously (Note: there may be specific risks of stopping and restarting abacavir, which should be addressed with the patient).
- Instruction on what to do if a medication dosage is unintentionally missed.
- Ample opportunity for the practitioner to ensure that the patient understands the medication regimen and is strongly committed to adhering to it.

Although safe-sex practices should always be encouraged, the potential for teratogenicity should be considered when choosing an ARV regimen for women of childbearing age.

Refer to Table 13 in the original guideline document for preferred, alternative, and contraindicated combinations of ARV agents. Table 14 in the original guideline document lists possible dose combinations for protease inhibitors.

Choosing an Initial HAART Regimen for Patients Previously Treated with Only Nucleoside Analogs

Patients who have been maintained on mono or dual nucleoside regimens and who have significant viral suppression and a relatively intact immune system may be observed without switching them to HAART.

Choice of HAART regimens in nucleoside-experienced patients with suboptimal response should be guided by results of HIV resistance studies.

Changing a Successful Initial HAART Regimen

When considering a change in ARV therapy in the setting of drug toxicity, it is important to confirm that viral load is maximally suppressed. Single drug substitution is appropriate for toxicity in the setting of maximal viral suppression.

Practitioners should not change an ARV regimen when there is incomplete but significant viral suppression (≥ 0.5 log reduction, or 3-fold, from baseline viral load value) compared with baseline and an effective rescue HAART regimen cannot be constructed as a result of drug resistance or intolerance.

Changing a successful initial HAART regimen for quality-of-life issues or fear of potential toxicities is appropriate if the patient's adherence will be compromised.

Failure to Achieve Goals of Initial HAART

Failure to demonstrate a 1.5- to 2.5-log drop in viral load within 3 months of treatment (see Table 3 in the original guideline document) and, more importantly, failure to achieve a viral load <50 copies/mL within 6 months (depending on baseline viral load) indicates unsuccessful HAART.

Viral resistance assays should be obtained before changing HAART regimens that have failed. If patient adherence has been optimized, patients whose HIV viral loads demonstrate a major reduction in the first several months of therapy but fail to suppress to <5,000 to 10,000 copies/mL may be considered for treatment "intensification" by adding another drug to the existing HAART regimen or enhancing drug levels through the use of pharmacologic boosting (e.g., ritonavir or delavirdine).

Therapy should not be altered for patients with maximal viral suppression, even when CD4 counts do not increase.

Rescue/Salvage HAART Therapy

Rescue/salvage therapy should be guided by laboratory tests of HIV drug resistance and individual ARV histories.

The use of agents in novel ARV classes, such as the fusion inhibitor enfuvirtide or T-20, should be considered when treating patients with pre-existing drug resistance.

Treatment of Acute HIV Infection

Practitioners should maintain a high level of suspicion for acute HIV infection in all patients presenting with a compatible clinical syndrome (see Table 15 in the original guideline document) and should immediately obtain appropriate laboratory testing (quantitative HIV RNA or p24 antigen).

Confirmatory HIV antibody testing should be performed 3 to 6 weeks after diagnosis by HIV RNA testing.

The potential benefits of therapy should be weighed against the potential risks, and the practitioner and the patient should be fully aware that therapy of primary HIV infection is of unproven efficacy.

The patient should be carefully counseled regarding potential limitations of HAART in acute primary infection, and individual decisions should be made only after weighing the risks and sequelae of therapy against the theoretical benefit of treatment.

Once the physician and patient have made the decision to use ARV therapy for primary HIV infection, treatment should be implemented with the goal of suppressing plasma HIV RNA levels to below detectable levels.

Management of HAART Treatment Interruption

Patients should be discouraged from stopping HAART without first consulting their practitioner.

If medically necessary, HAART can be interrupted (all drugs simultaneously) with a relatively low risk of the patient developing drug-resistant HIV.

Strategic treatment interruption is an experimental treatment approach and thus cannot be recommended outside of a research setting in the current management of the HIV-infected patient.

Referring Patients to Research Studies

Referral of patients to research protocols should be 1) to provide treatment or diagnostic options that may be otherwise unavailable and that may enhance treatment outcome, and 2) to attempt to answer a relevant research question.

Patients should be fully informed of any financial benefit their referral to a research study might have for the referring practitioner.

Patients should be informed that research studies often require major commitments of time and effort in addition to potential unforeseeable risk.

The practitioner should provide assistance to patients who want to participate in research studies.

Interactions Between HAART and Psychotropic Medications

Practitioners should refer to the prescribing information of all medications that patients are receiving to determine whether any significant drug interactions are likely to occur before initiating HAART or psychotropic therapy. Reviewing prescribing information is also recommended when mental status changes or onset of psychiatric symptoms are associated with recent alterations in HAART or psychotropic regimens.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Antiretroviral Therapy

- The preservation and/or restoration of immune function
- Improvement of overall health and the prolongation of life
- The suppression of viral replication
- The possible decrease in risk of viral transmission to others (including fetal transmission)

Early Therapy

- Control of viral replication is easier to achieve and maintain
- Delay or prevention of immune system compromise
- Lower risk of resistance with complete viral suppression
- Possible decreased risk of HIV transmission

Delayed Therapy

- Minimization of negative effects on quality of life
- Avoidance of drug-related adverse events
- Delayed development of drug resistance
- Preservation of maximum number of available and future drug options until risk of human immunodeficiency virus (HIV) disease progression is higher

POTENTIAL HARMS

Antiretroviral Therapy

- Adverse effects of the medications on quality of life (for adverse effects and drug interactions of specific antiretroviral drugs, see tables in appendices A-E of the original guideline)
- Known, and as yet unknown, long-term drug toxicities, including potential fetal toxicity
- The development of human immunodeficiency virus (HIV) drug resistance to drugs currently available and possibly to those not yet available, which may limit future treatment options

Early Therapy

- Drug-related reduction in quality of life
- Greater cumulative drug-related adverse events
- Earlier development of drug resistance if viral suppression is suboptimal
- Limitation in future ARV treatment options

Delayed Therapy

- Possible risk of further or irreversible immune system depletion
- Possible greater difficulty in suppressing viral load
- Potential increased risk of HIV transmission

CONTRAINDICATIONS

CONTRAINDICATIONS

See the appendices of the original guideline document for contraindicated combinations of antiretroviral drugs and other medications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines do not offer an exact recipe for treating human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) because there is no one right way to treat HIV. Like all practice guidelines, the guidelines provide information and advice to assist doctors and patients in making treatment decisions. One single approach doesn't fit each person. The guidelines can help doctors and patients decide what kind of approach may work best in each individual situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening, or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience.
- Define target audience (providers, consumers, support service providers)

Are there groups within this audience that need to be identified and approached with different strategies? (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)

- Define implementation methods

What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?

- Determine appropriate implementation processes
 - What steps need to be taken to make these activities happen?

- What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
- What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
- Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor Progress

What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?

- Evaluate
 - Did the processes and strategies work? Were the guidelines implemented?
 - What could be improved in future endeavors?

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Antiretroviral treatment of HIV infection. New York (NY): New York State Department of Health; 2003 Mar. 64 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Chair: Amneris Luque, MD, Assistant Professor of Medicine, University of Rochester Medical Center, Medical Director, AIDS Center, Strong Memorial Hospital

Committee Members: Bruce Agins, MD, MPH, Assistant Professor of Medicine, Cornell University Medical College, Medical Director, AIDS Institute, New York State Department of Health; Doug Fish, MD, Albany Medical College; Charles Gonzalez, MD, Assistant Professor of Medicine, New York University School of Medicine, Clinical Investigator, AIDS Clinical Trials Unit, New York University Medical Center - Bellevue Hospital Center; Harold Horowitz, MD, Professor of Medicine, New York Medical College, Medical Director, AIDS Care Center, Division of Infectious Diseases, Westchester Medical Center; Marc Johnson, MD, Attending Physician, New York Hospital Queens, Assistant Professor of Medicine, Mount Sinai School of Medicine, Physician in Charge, New York Hospital--Queens Primary Care at ACQC; Jessica Justman, MD, Division of Infectious Diseases, Bronx-Lebanon Hospital Center; Sharon Mannheimer, MD, Assistant Professor of Clinical Medicine, Columbia University College of Physicians and Surgeons, Harlem Hospital Center, Division of Infectious Diseases; Neal Rzepkowski, MD, HIV Care Consultant, New York State Department of Corrections, HIV Care Provider, Erie County Medical Center Rural Outreach, Chautouque County Department of Health HIV Clinics; Kent Sepkowitz, MD, Memorial Sloan-Kettering Cancer Center; Rona Vail, MD, HIV Care Provider, Attending Physician, Callen-Lorde Community Health Center; Barry Zingman, MD, Medical Director; AIDS Center, Montefiore Medical Center

Liaisons: Sheldon Brown, MD; Barbara Chaffee, MD, MPH; Joseph R. Masci, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Antiretroviral treatment of HIV infection. Tables and recommendations. New York (NY): New York State Department of Health; 2003 Mar. 48 p.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p.

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

PATIENT RESOURCES

The following is available:

- Making sense of HIV treatment. A patient's guide to the Federal antiretroviral therapy guidelines. New York (NY): New York State Department of Health; 2003. 66 p.

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was prepared by ECRI on January 21, 2004.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the guideline developer. See the [New York State Department of Health AIDS Institute Web site](#) for terms of use.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 4/12/2004

The logo for FIRSTGOV, featuring the word "FIRST" in blue and "GOV" in red, with a small red star above the "I" in "FIRST".

